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Patitioner's Docket No.

2260/103

PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pflaum, et al.

Application No.: 09/600,566

Group No.: 1651

Filed: February 17, 1999

Examiner: Irene Marx

For: Process for the Obtaining of HMG-CoA Reductase Inhibitors of High Purity

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. SECTION 1.97(c))

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under Section 1.113 or (2) a notice of allowance under Section 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of Section 1.97 or the fee set forth in Section 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

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☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

☐ transmitted by facsimile to the Patent and Trademark Office (703) ____-____.

Date: February 11, 2004

Signature

Barbara J. Carter, Ph.D.

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Before Mailing Date of Final Action or Notice of Allowance--page 1 of 3)

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applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

TIME OF TRANSMITTAL OF ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

(1) a final action under Section 1.113 or

(2) a notice of allowance under Section 1.311,

whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is

(check either A or B below)

A. ☐ a statement as specified in 37 C.F.R. Section 1.97(e).

OR

B. ☒ the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

Fee due \$ _____

METHOD OF PAYMENT OF FEE

4.

☒ Attached is a check in the amount of \$ 180.00.

☐ Charge Account No. _____ in the amount of \$ _____.

A duplicate of this request is attached.

If any additional fees are due, please charge Account #19-4972.

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02260/00103 294224.1



SIGNATURE OF PRACTITIONER

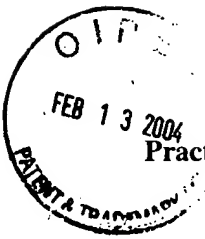
Barbara J. Carter, Ph.D.

(type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110



Practitioner's Docket No.

2260/103

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Pflaum, et al.

Application No.: 09/600,566

Group No.: 1651

Filed: February 17, 1999

Examiner: Irene Marx

For: Process for the Obtaining of HMG-CoA Reductase Inhibitors of High Purity

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 7)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

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TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: February 11, 2004

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Supplemental Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ JEPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Pflaum, et al. Attorney Docket: 2260/103
Serial No: 09/600,566 Art Group Unit: 1651
Date Filed: February 17, 1999 Examiner Name: Irene Marx
Invention: Process for the Obtaining of HMG-CoA Reductase Inhibitors of High Purity

LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AH	JP	A-6-506210 /	1994		C07D 493/08
	AI	WO	92/16276 /	10/1/1992	Merck & Co., Inc.	B01D 15/08

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	AJ	Chan, C., et al.	"Inhibitors of Cholesterol Biosynthesis. 1. 3,5-Dihydroxy-7-(N-imidazolyl)-6-heptenoates and -heptanoates, a Novel Series of hMG-CoA Reductase Inhibitors," <i>J. Med. Chem.</i> , 1993, vol. 36, pp. 3646-3657.
	AK	Procopiou, P., et al.	"Inhibitors of Cholesterol Biosynthesis. 2. 3,5-Dihydroxy-7-(N-pyrrolyl)-6-heptenoates and -heptanoates, a Novel Series of hMG-CoA Reductase Inhibitors," <i>J. Med. Chem.</i> , 1993, vol. 36, pp. 3658-3662.

Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to 37 CFR 1.98 9(a)(2)(i) and 37 CFR 1.491(b), in which the USPTO waived the requirement for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

Section 8. Translation(s) of Non-English Language Documents

NOTE: "If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in section 1.56(c), a copy of the translation shall accompany the statement." 37 C.F.R. section 1.98(c).

NOTE: "The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise explanation in section 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.

NOTE: "The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).

- ☐ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

(complete the following, if applicable)

- ☒ No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- ☒ The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith. **JP-A-6-506210 (an equivalent of US 668,831 ~~A~~CIP)**

Section 10. Identification of Person(s) Making This Supplemental Information Disclosure Statement

The person making this certification is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

Reg. No.: 52,703

Tel. No.: (617) 443-9292

Customer No.: 002101

02260/00103 294217.1



SIGNATURE OF PRACTITIONER

Barbara J. Carter, Ph.D.

(type or print name of practitioner)

125 Summer Street, 11th Floor

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Boston, MA 02110